

(19)



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11)

**EP 0 824 900 B1**

F

(12)

## EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention  
of the grant of the patent:  
**02.04.2003 Bulletin 2003/14**

(51) Int Cl.7: **A61F 2/06, A61L 27/00**

(21) Application number: **96309057.6**

(22) Date of filing: **12.12.1996**

### (54) Protective coating for a stent

Schutzbeschichtung eines Stents

Revêtement protecteur pour un Stent

(84) Designated Contracting States:  
**BE DE FR GB IT NL**

(30) Priority: **22.08.1996 US 701708**

(43) Date of publication of application:  
**25.02.1998 Bulletin 1998/09**

(60) Divisional application:  
**02007308.6 / 1 290 984**

(73) Proprietor: **Advanced Cardiovascular Systems,  
Inc.  
Santa Clara, CA 95052 (US)**

### (72) Inventors:

- **Callol, Joseph R.  
San Francisco, California 94114 (US)**
- **Yan, John Y.  
Sunnyvale, California 94086 (US)**

### (74) Representative:

**McLeish, Nicholas Alistair Maxwell et al  
Boulton Wade Tennant  
Verulam Gardens  
70 Gray's Inn Road  
London WC1X 8BT (GB)**

### (56) References cited:

**EP-A- 0 448 016                      EP-A- 0 679 372  
EP-A- 0 679 373                      WO-A-96/24393**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

## Description

[0001] The invention relates generally to stents, and more particularly to coatings applied to stents to make the same radiopaque and coatings to protect the stent.

[0002] Stents are useful in the treatment of atherosclerotic stenoses in blood vessels and are generally tubular shaped devices which function to hold open a segment of a blood vessel, artery, heart valve or other body lumen. Stents are particularly suitable for use in supporting and holding open a coronary artery after an atherectomy or angioplasty procedure.

[0003] Generally, stents are made from a metal alloy, such as stainless steel, and have a hollow tubular shape with an outer wall surface resembling an open lattice configuration. In some prior art stents, the outer wall surface comprises intersecting wires or struts that are expanded beyond the elastic limit thereof to plastically deform and hold open the body lumen in which they are implanted. Other stents are self-expanding and can be in the form of a coil wire that is biased open.

[0004] Stents made from stainless steel, for example, are radiolucent, due in part to the intersecting wires having a diameter of about 0.076 mm (0.003 in.) or less. Unless the metal or metal alloy used for making the stent has a high atomic weight and density, it is difficult to visualize in vivo during catheter introduction into the vessel, stent deployment, and post-operative diagnosis.

[0005] At least one prior art stent has an increased wire diameter, to approximately 0.102 mm (0.004 in.), in order to make the stent more radiopaque. The disadvantages of a stent having thicker intersecting wires is a more rigid stent that tracks poorly through a tortuous vessel, a stent which is virtually inflexible when tracking on a curved section of vessel, a stent that cannot be implanted easily in a curved section of a vessel, a stent which may not deploy in a uniform cylindrical shape, and a stent with poor hemodynamics. The latter disadvantage, poor hemodynamics, can result in serious medical complication such as thrombosis.

[0006] In order to increase the radiopacity of the stent without the disadvantage of thicker wires, the stent may be provided with a radiopaque marker.

EP-A-0,679,372 describes a radiopaque marker associated with a stent which is adapted to be implanted into a body lumen of a patient to maintain the patency thereof and a convenient and accurate method for affixing the radiopaque marker to the stent. The radiopaque marker defines an acceptable profile and is capable of facilitating, under fluoroscopy, the identification of the position, diameter and length of a stent without obscuring the lesion being repaired and without impeding the deformation of an expandable stent.

[0007] By contrast, EP-A-0,679,373 describes an intravascular stent coated with a parylene polymer, to reduce thrombogenesis and restenosis.

[0008] According to a first aspect of the present invention there is provided a stent for implanting in a body

lumen, comprising: an elongated tubular body formed from a first metallic material and being substantially radiolucent; and a protective layer covering the elongated tubular body, characterised in that the stent further comprises a radiopaque layer formed from a second metallic material and covering at least a portion of the protective layer so that the stent is visible under fluoroscopic X-ray, the protective layer reducing the likelihood of galvanic corrosion between the radiopaque layer and the elongated tubular body. tubular body.

[0009] Thus the disadvantages of the prior art stents are addressed by embodiments of the present invention in which a stent is provided that is sufficiently radiopaque, flexible, has a low profile, is substantially non-thrombogenic, and has a protective layer that will eliminate corrosion

[0010] For example, a stent may comprise an elongated tubular body that is substantially radiolucent and formed from, for example, a stainless steel alloy. In order to increase the radiopacity of the stent, without the disadvantages of thicker wires, the stent, or a portion thereof, may be coated with a thin radiopaque layer of material having high atomic weight, high density, sufficient surface area and sufficient thickness. With such a coating, the stent is sufficiently radiopaque to be seen with fluoroscopy, yet not so bright as to obstruct the radiopaque dye. This radiopaque layer is made of a different material to the elongated tubular body and covers at least a portion of the stent. This radiopaque layer can be formed from gold, tantalum, platinum, bismuth, iridium, zirconium, titanium, barium, silver, tin, alloys of these metals, or similar materials.

[0011] The radiopaque layer is thin, in one preferred embodiment it is about 1.0 to 50 microns thick.

[0012] However, whenever two dissimilar metals are in direct contact, such as a stainless steel stent at least partly covered with a gold radiopaque layer, there is the potential to create the electrochemical reaction that causes galvanic corrosion. The by-product of corrosion (i.e., rust) will not be biocompatible or blood compatible, may cause a toxic response, and may adversely affect adhesion of the radiopaque material. Corrosion will occur if gold and another metal, like stainless steel, are in contact with the same bodily fluid (electrolyte). If the gold coating has any pinholes or has a flaked or scratched-off surface, the underlying stainless steel will be exposed to the same fluid. Therefore, a galvanic reaction (i.e., a battery effect) will occur. The use of a single protective coating disposed between the radiopaque layer and the body and covering the surface of the body prevents this reaction. As a result the stent is biocompatible.

[0013] Other aspects of the invention include a method according to claim 9 of making the stent and of applying a protective layer and a radiopaque layer to it. The radiopaque coating can be applied by dipping, spraying, painting, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, la-

ser welding or fusing, resistance welding, and ion implantation. The protective layer can be applied by dip coating, spray coating, spin coating, plasma deposition, condensation, electrochemically, electrostatically, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, ion implantation, or use of a fluidized bed. The process for applying the protective layer and the radiopaque layer depends upon numerous factors which can include the type of material comprising the layer.

[0014] These and other advantages of the invention will become more apparent from the following detailed description and the accompanying drawings. While they show arrangements which are not examples of the invention, the drawings and accompanying description are useful for understanding the invention and how it may be put into practice.

[0015] FIGURE 1 is a perspective view depicting a stent having an open lattice structure and covered with both a radiopaque layer and a protective layer.

[0016] FIG. 2 is a cross-sectional view of the stent of FIG. 1 taken along lines 2-2, depicting the stent covered by a radiopaque layer and a protective layer over the radiopaque layer.

[0017] FIG. 3 is a cross-sectional view of one of the wires of the stent of FIG. 2 taken along lines 3-3, depicting the stent wire being coated with a radiopaque layer and a protective layer.

[0018] FIG. 4 is a perspective view of a stent having an open lattice structure and being partially covered by a radiopaque layer and completely covered by a protective layer.

[0019] FIG. 5 is a cross-sectional view taken along lines 5-5 of the stent of FIG. 4, depicting a partial radiopaque layer on the stent, covered by a protective layer.

[0020] FIG. 6 is a cross-sectional view taken along lines 6-6 of the stent of FIG. 5, depicting a straight portion of a stent wire having a radiopaque layer covered by a protective layer.

[0021] A stent embodying the invention may be intended for either temporary or permanent deployment in a body lumen such as a coronary artery, carotid artery, vessels in the brain, aorta, peripheral arteries and veins, and the like. The stent also can be deployed in the urethra and other body lumens. The stent is used primarily to support the body lumen so that it remains patent and permits the uninterrupted flow of blood or other body fluids. It is important for purposes of delivery, deployment and post-operative diagnosis that the stent be both visible and remain biocompatible. A stent embodying the invention is visible due to a radiopaque layer and it remains biocompatible due its protective layer.

[0022] A stent that is made by known etching processes or laser cutting a metal tube, or by winding a metal wire(s), must be sufficiently thick to be radiopaque under X-ray or fluoroscopy *in vivo*. Generally, current stent designs include an open lattice structure of interwoven wires or struts or coils that are made from stainless steel

or other metals or metal alloys that are radiolucent due to a wire thickness or cross-section of about 0.076 mm (0.003 in.) or less. Unless the metal or alloy used for making the stent has high atomic weight and density, it is difficult to visualize the stent *in vivo* during catheter introduction into the vessel (artery, vein, urethra, etc.), stent deployment, and post-operative diagnosis. Another solution to increase radiopacity of the stent is to increase the strut or wire cross-section to approximately 0.102 mm (0.004 in.), however, this will result in a substantially more rigid stent having poor hemodynamics.

[0023] Thickening the stent or changing the material used for making the stent to a more radiopaque material (i.e., tantalum, gold, etc.) may lead to poor stent performance. A thicker, high profile stent may result in areas of stagnation, turbulence, separation of flow, or other unacceptable fluid dynamics that can promote thrombogenesis. A thicker stent has lower fatigue resistance due to its brittleness. A tantalum stent is brittle and cracks easily. A gold stent will be prohibitively expensive and too ductile. In the thickness range of less than 0.076 mm (0.003 in), a gold stent will not have sufficient strength to support the artery or body lumen. Both will be too radiopaque (stent made from all tantalum or gold) and will obstruct the view of radiopaque dye when it flows through the lumen of the stent. Allowing visualization of the dye flowing through the stent lumen is important for diagnostics. Dye flowing through the stent lumen provides information to the clinician about restenosis, the size of artery, the size of the stent lumen during and after deployment, and the presence of dilation or other important parameters necessary for the care of the patient. This avoids the need for post-insertion and post-operative ultrasound detection procedures necessary to determine the diameters of the stent and vessel lumen. Therefore, a thin radiopaque coating is preferred over a stent made entirely from a highly radiopaque material.

[0024] Coating the stent with a thin layer of material having high atomic weight, high density, sufficient thickness (15 microns or less), and large surface area will have an effect similar to that of thickening the stent. It will make the stent sufficiently radiopaque so that it can be seen, *in vivo* but not so radiopaque to obstruct the view of radiopaque dye. The coating can be high atomic weight material such as gold, tantalum, platinum, bismuth, iridium, or the like. It also can be lower atomic weight material like zirconium, titanium, barium, silver, tin, or the like. For the latter-type coatings, a thicker coating may be needed to make the stent sufficiently radiopaque. In either case, a thin coating will allow the stent to remain thin and flexible while maintaining a low stent profile to minimize disruption of blood flow.

[0025] Gold is the preferred radiopaque coating because of its high atomic weight and density, both of which contribute to its radiopacity. In addition, gold is a highly ductile metal and therefore, resists cracking when the stent is stressed during deployment or fatigue after deployment. A thin gold coating (less than 15 microns)

is sufficient to absorb enough energy to be opaque when exposed to X-rays. Equivalent radiopacity cannot be achieved with a stent made from stainless steel or the like unless the stent is at least twice the thickness. Studies have shown that a 2.0 to 3.0 micron gold coating (or other metal) on a 0.058 mm (0.0023 in.) thick 316L stainless steel stent (i.e., where the diameter of the wires or struts is 0.058 mm (0.0023 in.)) is sufficient to elevate the radiopacity to make it equivalent in radiopacity to a 0.102 mm (0.004 in.) thick 316L stent.

**[0026]** When dissimilar metals come in contact, such as the gold radiopaque coating on a stainless steel stent, the potential to initiate galvanic corrosion exists. This phenomenon occurs when two electrochemically dissimilar metals come in contact with each other.

**[0027]** In order to reduce galvanic corrosion it is essential to coat the outermost surface of the stent with a protective coating. The protective coating prevents the electrochemical reaction that causes galvanic corrosion, and is blood and tissue compatible. It is thin and flexible such that it will not crack during stent deployment. It will hide any flaws that are on the surface of the stent and prevent any extraordinary events from occurring. In addition, it has a lower coefficient of friction than most stent materials. A hydrogel layer also can be applied on the inside and/or outside surface of the stent by chemically bonding it to this protective coating. The hydrogel coating then can act as a buffer between the stent and vessel, minimizing vascular injury.

**[0028]** Figs. 1-2, depict a stent 10 being of a generally cylindrical member having an elongated tubular body 11 with an outer surface 12 and an inner surface 13. When the stent 10 is made from a material that is substantially radiolucent, it is important to increase its radiopacity. In order to increase the visibility of the stent 10, a radiopaque layer 14 is applied to coat all of the stent 10, including the outer surface 12 and the inner surface 13. Typically, the stent 10 will be made from a plurality of intersecting struts or wires 15 that can be formed by known methods as described herein. In this arrangement, the radiopaque layer 14 is applied so that it covers all portions of the struts or the wires 15. As is shown in Fig. 3, the radiopaque layer 14 surrounds the strut 15 so that its radiopacity is ensured. It is preferred that the radiopaque layer 14 have a uniform thickness in the range of 1.0 to 50 microns and, more preferably, in the range of from 1.5 to 10 microns. If the radiopaque layer 14 is too thick, it also may result in the stent 10 being too bright under fluoroscopy and it may interfere with the expansion of the stent. Thus, the thickness of radiopaque layer should be uniform and in the preferred thickness ranges, depending upon such factors as the type of metal in the stent, where it will be implanted, the diameter of the struts 15, and the like.

**[0029]** As shown in Figs. 1-3, a protective layer 20 covers and surrounds the radiopaque layer 14 and protects it against scratches, flaking, and other mishandling. Generally, the radiopaque layer 14 will be formed

from a relatively soft and malleable metal such as gold, and it is subject to scratching and flaking both before it is delivered in the patient and after it is mounted on a catheter and delivered intraluminally. Thus, the protective layer 20 will provide a durable coating to protect the radiopaque layer.

**[0030]** The stent 10 and the radiopaque layer 14 are formed from dissimilar metals which may initiate the chemical reaction leading to galvanic corrosion. The protective layer 20 completely coats the radiopaque layer 14 thereby eliminating any likelihood of galvanic corrosion.

**[0031]** Figs. 4-6 depict the stent 10 only partially coated by a partial radiopaque layer 30. Portions of the stent 10 are coated with the partial radiopaque layer 30, while the stent portion 31, which is curved, is not covered by a radiopaque layer. It is noted that the scale of the partial radiopaque layer 30 to the stent struts 33 and the protective layer 34 is somewhat out of proportion for ease of illustration. Typically, as has been demonstrated in experiments, the partial radiopaque layer 30 is applied to straight sections 32 of the struts 33 so that the stent can be expanded without distortion. Many commercial stents have curved sections and curved struts that will twist and deform if the radiopaque layer is applied to the curved section, since the radiopaque layer actually adds some rigidity to the stent. Thus, the partial radiopaque layer 30 may be applied to the non-curved struts of the stent. In other stent configurations, it may not matter where the partial radiopaque layer 30 is applied on the stent 10. The primary reason for the radiopaque layer is to enhance the visibility of the stent, but it should not interfere with stent expansion.

**[0032]** In Figs. 4-6, the stent 10 is coated by a protective layer 34, which actually covers the stent portion 31 and the partial radiopaque layer 30. The protective layer 34 eliminates the possibility of galvanic corrosion as a result of the stent 10 and the partial radiopaque layer 30 being of dissimilar metals.

**[0033]** In another arrangement the protective layer 34 covers only the partial radiopaque layer 30 and does not cover those portions of the stent 10 where there is no radiopaque coating. Thus, using FIG. 4 as an example, the partial radiopaque layer 30 is applied to straight sections 32 and the protective coating 34 is selectively applied to cover the partial radiopaque layer 30 only.

**[0034]** The radiopaque coating can be made from solid metal (i.e., gold, silver, tin, tantalum, zirconium, platinum, or other metals).

**[0035]** The radiopaque coating can be coated anywhere on the stent. It can partially cover the stent (one or more bands, longitudinal continuous or discontinuous band, dots, outside surface only, inside surface only, etc.) or fully cover the stent.

**[0036]** In one method of applying the radiopaque layer 14 or the partial radiopaque layer 30, a radiopaque coating can be applied by dipping, spraying, painting, electroplating, evaporation, plasma vapor deposition, ca-

thodic arc deposition, sputtering, ion implantation, laser welding or fusion, resistance welding, or other methods. The thickness of the radiopaque coating generally is 50 microns or less. The coating can be applied on the inside and/or outside surface of the stent or it can fully encapsulate the stent strut(s).

[0037] For instance, a band of gold coating can be placed around the stent at the ends by first completely masking the stent with alkaline or acid-resistant mask material (i.e., the material manufactured under the tradename "MICROSTOP" by Pyramid Chemical Company, polyesters, acrylic, wax, etc.). The type of mask material depends on what coating process is to be used. After the stent has been masked, the mask is removed preferentially from the stent surface, using a laser, sandblaster, or other appropriate method. Any pattern can be made by selectively removing mask material. The exposed surface (non-masked areas) then can be coated with radiopaque material by the above-described methods (i.e., electroplating). Other masking techniques also are possible (i.e., physical, chemical, or mechanical). In addition, prefabricated gold markers also can be laser-fused or resistance-welded to the stent at any specific locations. Further details of applying a radiopaque layer to a stent are found in co-pending European Patent Application EP-A-0,679,372.

[0038] In one method of applying the protective layer 30,34, the biocompatible and blood-compatible protective layer can be polymeric, "PARYLAST", polymethylene, or ceramic. A polymeric layer (i.e., parylene, polycarbonate-urethane copolymer, silicone rubber, hydrogels, polyvinyl alcohol, polyvinyl acetate, polycaprolactone, urethanes, PHEMA-Acrylic, etc.) can be applied onto the radiopaque-coated stent by dip-coating, spray-coating, spin-coating, plasma deposition, condensation, electrochemically, electrostatically, or other suitable methods. "PARYLAST" is a preferred protective coating and is distributed by Advanced Surface Technology Corp.

[0039] A ceramic coating (i.e., zirconium nitride, pyrolytic carbon, graphite, a material sold under the tradename "NEDOX" by the General Magnaplate Corporation, and titanium nitride) can be applied by the use of a fluidized bed, spraying, plasma-vapor deposition, evaporation, sputtering, electrochemically, electrostatically, a combination of the above, or the like. The thickness of the protective layer preferably is from .01 to 25 microns.

[0040] In an example of the present invention, not shown in the drawings, the protective layer is first applied to cover the stent and the radiopaque is applied to partially or completely cover the protective layer. In this embodiment, the radiopaque layer is scratch resistant and biocompatible.

[0041] A protective layer has been described herein as a mechanical barrier which protects against mishandling, the electrochemical reaction that causes galvanic corrosion, and against adverse blood and tissue re-

sponse. It also is important that the protective layer form a conformal coating that will adhere to the stent surface. When there is no adhesion, any stretching and straining of the stent may lead to a rupture of the protective layer, resulting in folds at the strained areas (like elephant skin folds) which may lead to a penetration of blood and tissue causing an adverse response, or causing galvanic corrosion.

[0042] Thus, with respect to all of the protective layers disclosed herein, the process to improve adhesion between the protective coating and the substrate is desired. One such process is to deposit a thin intermediate layer or layers from the silane group or to plasma deposit a polymer from a gaseous organic such as methane, xylene or gases from the silane or titanate groups. A preferred method is to deposit "PARYLAST," a coating which incorporates the deposition of an intermediary followed by parylene C in the same processing chamber. In addition to an intermediary layer, improved adhesion can be attained by reducing the thickness of the protective coating. Thinner coatings tend to be more flexible, especially when the material has a glass transition temperature above room temperature. Thus, thinner coatings adhere better.

[0043] Thus, a preferred method is to deposit "PARYLAST," a parylene C coating, which incorporates the addition of an intermediary in the same process chamber.

[0044] Another method for improving the adhesion between the protective layer and the radiopaque layer is by acid treatment, sandblasting, or similar methods. These methods allow a mechanical interlocking between the substrate and the protective layer.

[0045] "PARYLAST" can be coated at different thicknesses that can vary from 0.013 mm to 0.0025 mm (.00005 in. to .0001 in.). It is preferred that the thickness of the "PARYLAST" be at least 0.0025 mm (0.0001 in.) in order to minimize the potential for pinhole formation, while maintaining the optimum flexibility (thicker coatings may be too rigid and affect stent expansion). The degree of texture on the substrate may vary from 1 to 250 micron average pore sizes. It is preferred that the substrate have a 1-6 micron average pore size. At larger pore sizes, the textured surface is retained on the coated surface after parylene C or a "PARYLAST" treatment.

## Claims

1. A stent (10) for implanting in a body lumen, comprising:

an elongated tubular body (11) formed from a first metallic material and being substantially radiolucent; and  
a protective layer (20) covering the elongated tubular body, characterised in that the stent (10) further comprises a radiopaque layer (30)

formed from a second metallic material and covering at least a portion of the protective layer (20) so that the stent (10) is visible under fluoroscopic X-ray, the protective layer (20) reducing the likelihood of galvanic corrosion between the radiopaque layer and the elongated tubular body.

2. The stent (10) of claim 1, wherein the radiopaque layer (30) is scratch resistant and biocompatible.

3. The stent (10) of claim 1 or claim 2, wherein said first metallic material is taken from the group of metallic materials including stainless steel, nickel-titanium, tantalum, and titanium.

4. The stent (10) of any preceding claim, wherein the elongated tubular body (11) has a wall surface made up of a plurality of struts (15) each having a diameter of less than about 0.102 mm (0.004 inc.).

5. The stent (10) of any preceding claim, wherein the protective layer (20) has a thickness in the range of approximately .01 to 25 microns.

6. The stent (10) of any preceding claim, wherein the protective layer is biocompatible and blood compatible.

7. The stent (10) of any preceding claim, wherein the protective layer (20) is formed from a polymeric material taken from the group of polymeric materials including parylene, polymethylene, polycarbonate-urethane copolymer, silicone rubber, hydrogels, polyvinyl alcohol, polyvinyl acetate, polycaprolactone, urethanes, and PHEMA-Acrylic.

8. The stent (10) of any of claims 1 to 6, wherein the protective layer (2) is formed from a ceramic material taken from the group of ceramic materials including zirconium nitrite, graphite, pyrolytic carbon and titanium nitrite.

9. A method of protecting a stent from an electrochemical reaction that causes galvanic corrosion, the method comprising the steps of:

providing an elongated tubular body (11) formed from a first metallic material and being substantially radiolucent; and  
applying a protective layer (20) on the elongated tubular body (11), **characterised in that** the method further comprises the step of applying a radiopaque layer (30) formed from a second metallic material on at least a portion of the protective layer (20) so that the stent (10) is visible under fluoroscopic X-ray, the protective layer (20) reducing the likelihood of galvanic corro-

sion between the radiopaque layer and the elongated tubular body.

10. The method of claim 9, wherein the protective layer (20) is applied by a process selected from the list comprising dipping, spraying, spin coating, plasma deposition, condensation, electrostatically, electrochemically, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, ion implantation or use of a fluidized bed.

11. The method of claim 9 or claim 10, wherein the radiopaque layer (14) is applied by a process selected from the list comprising dipping, painting, electroplating, evaporation, plasma vapor deposition, cathodic arc deposition, sputtering, laser welding or fusion, resistance welding or ion implantation.

## Patentansprüche

1. Stent (10) zur Implantation in ein Körperlumen, umfassend:

einen länglichen, röhrenförmigen Körper (11), der aus einem ersten metallischen Material gebildet ist und im Wesentlichen röntgenstrahlendurchlässig ist;

und

eine Schutzschicht (20), die den länglichen, röhrenförmigen Körper bedeckt, **dadurch gekennzeichnet, dass** der Stent (10) darüber hinaus eine röntgenstrahlenundurchlässige Schicht (30) umfasst, die aus einem zweiten metallischen Material gebildet ist und wenigstens einen Teil der Schutzschicht (20) bedeckt, so dass der Stent (10) unter fluoroskopischen Röntgenstrahlen sichtbar ist, wobei die Schutzschicht (20) die Wahrscheinlichkeit galvanischer Korrosion zwischen der röntgenstrahlenundurchlässigen Schicht und dem länglichen, röhrenförmigen Körper verringert.

2. Stent (10) nach Anspruch 1, wobei die röntgenstrahlenundurchlässige Schicht (30) kratzfest und biokompatibel ist.

3. Stent (10) nach Anspruch 1 oder Anspruch 2, wobei das erste metallische Material aus einer Gruppe von metallischen Materialien stammt, zu denen Edelstahl, Nickel-Titan, Tantal und Titan zählen.

4. Stent (10) nach einem der vorangehenden Ansprüche, wobei der längliche, röhrenförmige Körper (11) eine Wandoberfläche aufweist, die eine Vielzahl von Streben (15) umfasst, welche jeweils einen Durchmesser von weniger als ungefähr 0,102 mm (0,004 Zoll) aufweisen.

5. Stent (10) nach einem der vorangehenden Ansprüche, wobei die Schutzschicht (20) eine Dicke im Bereich von ungefähr 0,01 bis 25 Mikrometer aufweist.
6. Stent (10) nach einem der vorangehenden Ansprüche, wobei die Schutzschicht biokompatibel und blutkompatibel ist.
7. Stent (10) nach einem der vorangehenden Ansprüche, wobei die Schutzschicht (20) aus einem Polymermaterial gebildet ist, das aus der Gruppe der Polymermaterialien einschließlich Parylen, Polymethylen, Polycarbonat-Urethan-Copolymer, Silikon gummi, Hydrogele, Polyvinylalkohol, Polyvinylacetat, Polycaprolacton, Urethane und PHEMA-Acryl stammt.
8. Stent (10) nach einem der Ansprüche 1 bis 6, wobei die Schutzschicht (20) aus einem Keramikmaterial gebildet ist, das aus der Gruppe der Keramikmaterialien einschließlich Zirkoniumnitrit, Graphit, pyrolytisches Carbon und Titanitrit stammt.
9. Verfahren zum Schutz eines Stents vor einer elektrochemischen Reaktion, die eine galvanische Korrosion bewirkt, wobei das Verfahren die folgenden Schritte umfasst:  
  
Vorsehen eines länglichen, röhrenförmigen Körpers (11), der aus einem ersten metallischen Material gebildet ist und im Wesentlichen röntgenstrahlendurchlässig ist; und Anbringen einer Schutzschicht (20) an dem länglichen, röhrenförmigen Körper (11), **dadurch gekennzeichnet, dass** das Verfahren darüber hinaus den Schritt des Anbringens einer aus einem zweiten metallischen Material gebildeten röntgenstrahlenundurchlässigen Schicht (30) an wenigstens einem Teil der Schutzschicht (20) umfasst, so dass der Stent (10) unter fluoroskopischen Röntgenstrahlen sichtbar ist, wobei die Schutzschicht (20) die Wahrscheinlichkeit galvanischer Korrosion zwischen der röntgenstrahlenundurchlässigen Schicht und dem länglichen, röhrenförmigen Körper verringert.
10. Verfahren nach Anspruch 9, wobei die Schutzschicht (20) mittels eines aus der folgenden Liste gewählten Verfahrens aufgebracht wird, umfassend Tauschen, Sprühen, Schleuderbeschichtung, Plasmaspritzen, Kondensierung, elektrostatisch, elektrochemisch, Elektroplattieren, Aufdampfen, Plasma-Aufdampfen, Kathodenzerstäubung durch Bogenentladung, Zerstäubung, Ionenimplantation oder Verwendung eines Fließbetts.
11. Verfahren nach Anspruch 9 oder Anspruch 10, wo-

bei die röntgenstrahlenundurchlässige Schicht (14) mittels eines aus der folgenden Liste gewählten Verfahrens aufgebracht wird, umfassend Tauschen, Auftragen, Elektroplattieren, Aufdampfen, Plasma-Aufdampfen, Kathodenzerstäubung durch Bogenentladung, Zerstäubung, Laserschweißen oder Laserfusion, Widerstandsschweißen oder Ionenimplantation.

## Revendications

1. Stent (10) destiné à être implanté dans une lumière corporelle, comprenant :

un corps tubulaire allongé (11) formé d'un premier matériau métallique et sensiblement radiotransparent ; et

une couche de protection (20) recouvrant le corps tubulaire allongé, **caractérisé en ce que** le stent (10) comprend en outre une couche radio-opaque (30) formée d'un second matériau métallique et recouvrant au moins une partie de la couche de protection (20) afin que le stent (10) soit visible par fluoroscopie, la couche de protection (20) réduisant la probabilité d'une corrosion galvanique entre la couche radio-opaque et le corps tubulaire allongé.

2. Stent (10) de la revendication 1, dans lequel la couche radio-opaque (30) est résistante à la rayure et biocompatible.
3. Stent (10) de la revendication 1 ou de la revendication 2, dans lequel ledit premier matériau métallique est choisi dans le groupe des matériaux métalliques comprenant l'acier inoxydable, le nickel-titane, le tantale et le titane.
4. Stent (10) de l'une quelconque des revendications précédentes, dans lequel le corps tubulaire allongé (11) a une surface de paroi faite d'une pluralité de nervures (15) ayant chacune un diamètre inférieur à environ 0,102 mm (0,004 pouce).
5. Stent (10) de l'une quelconque des revendications précédentes, dans lequel la couche de protection (20) a une épaisseur dans l'intervalle d'environ 0,01 à 25 microns.
6. Stent (10) de l'une quelconque des revendications précédentes, dans lequel la couche de protection est biocompatible et hémocompatible.
7. Stent (10) de l'une quelconque des revendications précédentes, dans lequel la couche de protection (20) est formée d'un matériau polymère choisi dans le groupe des matériaux polymères comprenant le

parylène, le polyméthylène, un copolymère de polycarbonate-uréthane, un caoutchouc de silicone, des hydrogels, l'alcool polyvinylique, l'acétate de polyvinyle, la polycaprolactone, des uréthanes, et le PHEMA-Acrylic.

5

8. Stent (10) de l'une quelconque des revendications 1 à 6, dans lequel la couche de protection (2) est formée d'un matériau céramique choisi dans le groupe des matériaux céramiques comprenant le nitrite de zirconium, le graphite, le carbone pyrolytique et le nitrite de titane.

10

9. Procédé pour protéger un stent d'une réaction électrochimique qui provoque une corrosion galvanique, le procédé comprenant les étapes consistant à :

15

utiliser un corps tubulaire allongé (11) formé d'un premier matériau métallique et sensiblement radiotransparent ; et  
appliquer une couche de protection (20) au corps tubulaire allongé (11), **caractérisé en ce que** le procédé comprend en outre l'étape consistant à appliquer une couche radio-opaque (30) formée d'un second matériau métallique sur au moins une partie de la couche de protection (20) afin que le stent (10) soit visible par fluoroscopie, la couche de protection (20) réduisant la probabilité d'une corrosion galvanique entre la couche radio-opaque et le corps tubulaire allongé.

20

25

30

10. Procédé de la revendication 9, dans lequel la couche de protection (20) est appliquée par un procédé choisi dans la liste comprenant le trempage, la pulvérisation par rotation, le dépôt au plasma, la condensation, par voie électrostatique, par voie électrochimique, le placage électrique, le dépôt en phase vapeur au plasma, le dépôt à l'arc cathodique, la projection de gouttelettes, l'implantation d'ions ou l'utilisation d'un lit fluidisé.

35

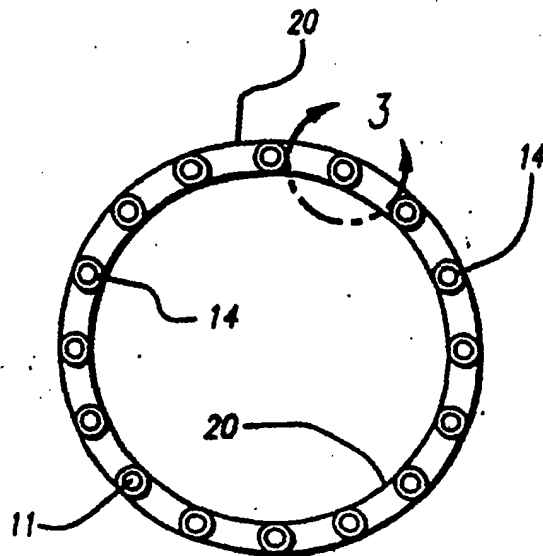
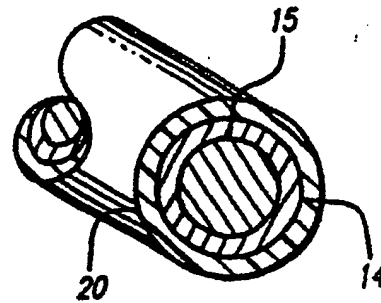
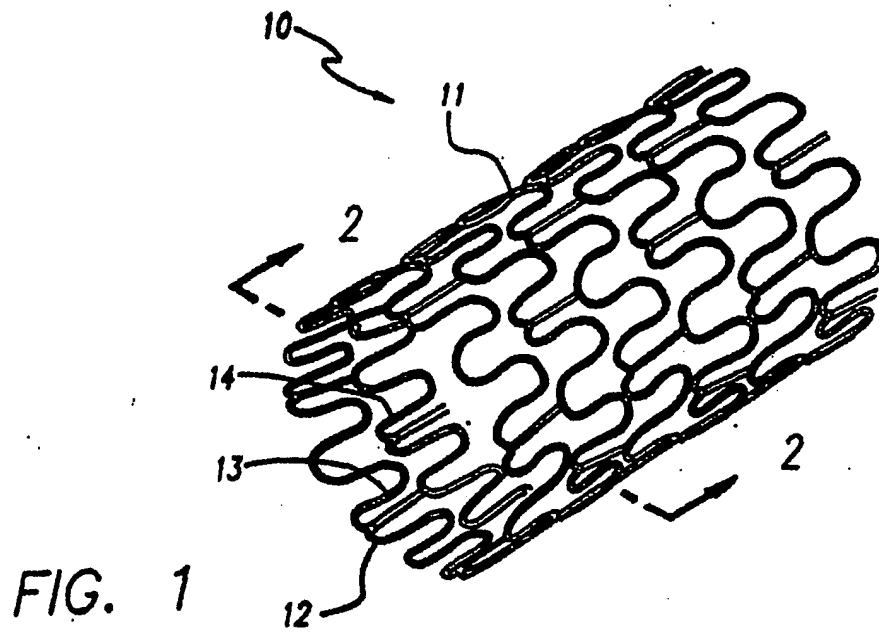
40

11. Procédé de la revendication 9 ou de la revendication 10, dans lequel la couche radio-opaque (14) est appliquée par un procédé choisi dans la liste comprenant le trempage, la peinture, le placage électrique, l'évaporation, le dépôt en phase vapeur au plasma, le dépôt à l'arc cathodique, la projection de gouttelettes, la soudure à l'arc ou par fusion, la soudure à résistance ou l'implantation d'ions.

45

50

55



BEST AVAILABLE COPY

FIG. 4

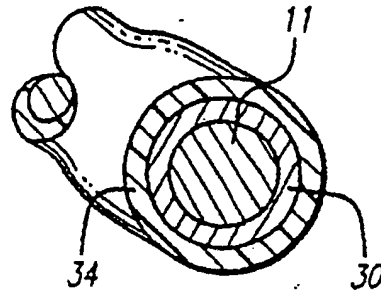
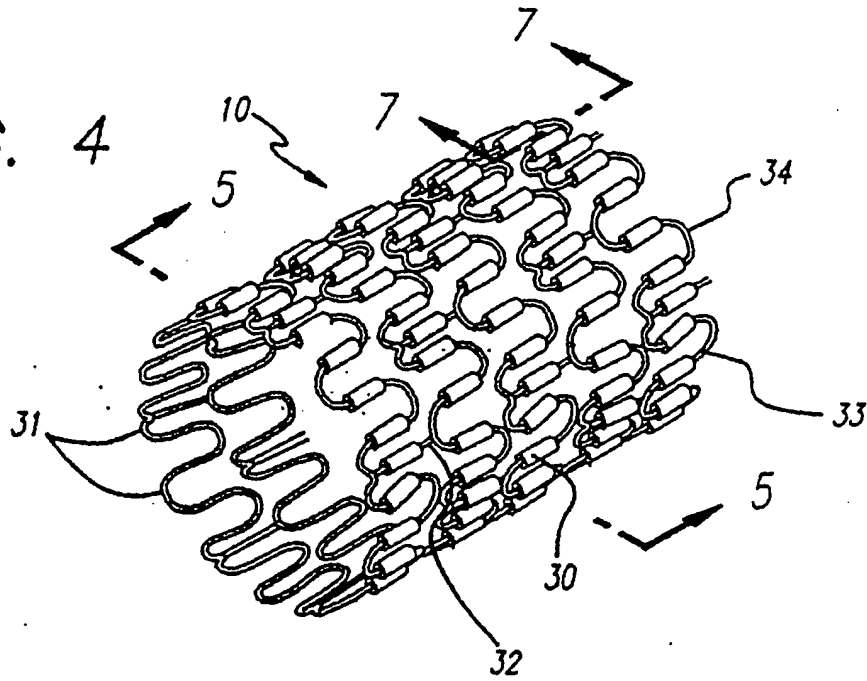


FIG. 6

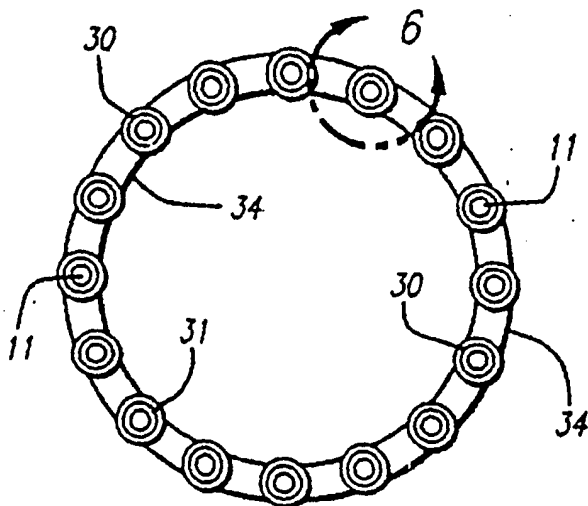


FIG. 5

BEST AVAILABLE COPY